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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,559	05/14/2002	Masayuki Yanagi	2026-4302US	8862
27180	7590	11/17/2005	EXAMINER	
ISIS PHARMACEUTICALS INC 1896 RUTHERFORD RD. CARLSBAD, CA 92008			LI, BAO Q	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/980,559

Applicant(s)

YANAGI ET AL.

Examiner

Bao Qun Li

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-11 and 37-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2-11 and 37 is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. <u>10/27&amp;31, 2005</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet</u> .  |

Continuation of Attachment(s) 6). Other: Quayle Action & examiner's amendment.

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### Quayle Action

1. This application is in condition for allowance except for the following formal matters:

1). On page 30, please add the sequence identification numbers (SEQ ID Nos:) to the primers disclosed in Table 1.

2). Please comply with the sequence rule for the sequence disclosures in Figures 3 and 6-7 of the drawings.

Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Nancy Vensko on October 27, 31, and November 01, 2005.

The application has been amended as follows:

Claim 2 (current amended). In line 4-5, please delete "or encodes an amino acid sequence that differs from that of SEQ ID NO: 2 by < 2.2% at the amino acid level"

Claim 3 (current amended). In line 2-4, please delete "or comprising a nucleic acid sequence that differs from that of SEQ ID NO: 1 from nucleotide 341-9439, which encodes to the ORF, by < 4.1% at the amino acid level"

Claim 4 (current amended). In line 2, please delete "or 38"

Claim 5 (current amended). In line 2, please delete "or 39"

Claim 8 (current amended). In line 1, please delete "A" and insert --- An in vitro ---

Claim 9 (current amended). In line 1, please delete "A" and insert --- An in vitro ---

Claim 10 (current amended). In line 1, please delete "A" and insert --- An in vitro ---

Claim 11 (current amended). In line 1, please delete "A" and insert --- An in vitro ---

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Claim 37 (current amended). In line 1, please insert --- claim 2 or 3 --- and in line 2, please delete "claim 2, 3, 38 or 39"

Please cancel claims 38-39.

Claims 2-11 and 37 are allowed.


2. The following is an examiner's statement of reasons for allowance: No prior art teaches and suggests the isolated nucleic acid molecule which encodes a particular mutated HCV genotype 2a isolate, HCV J6-CH, wherein said nucleic acid molecule has nucleic acid sequence of SEQ ID NO: 1, which encodes an amino acid sequence of SEQ ID NO: 2.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Bao Qun Li, MD  
11/01/2005

  
James Housel (SPE) 11/14/05  
Art Unit 1648

JAMES HOUSEL  
SUPERVISORY PATENT EXAMINER  
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